In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-361V

(not to be published)

MICHAEL BULL,	*	
	*	
	*	Chief Special Master Corcoran
Petitioner,	*	
	*	
v.	*	Filed: April 20, 2021
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

Mark T. Sadaka, Mark T. Sadaka, LLC, Englewood, NJ, for Petitioner.

Mollie D. Gorney, U. S. Dep't of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On March 8, 2018, Michael Bull filed a petition for compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program"[2]) alleging that he suffered from a non-specific "vaccine-induced neuropathy" as a result of receiving an influenza ("flu") vaccine on October 5, 2016, or alternatively that the above-stated vaccination significantly aggravated a pre-

[1] Although this Decision is not formally designated for publication, it will nevertheless be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire Decision will be available to the public in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

existing left-arm neuropathy. *See* Petition, filed March 8, 2018 (ECF No. 1) ("Pet.").[3] Despite a fact hearing and my urgings, the parties were unable to settle the matter, and therefore agreed to resolve the claim via ruling on the record. *See* Respondent's Motion to Dismiss, dated November 17, 2020 (ECF No. 49) ("Mot."); Petitioner's Response, filed Dec. 15, 2020 (ECF No. 54) ("Opp."); Respondent's Reply, dated Jan. 14, 2021 (ECF No. 56) (Resp.'s Reply"); Petitioner's Sur-Reply, dated Jan. 27, 2021 (ECF No. 57) (Pet.'s Sur-Reply"). This matter is now fully briefed and ripe for a ruling on the record.

As discussed below, Petitioner's claim is inadequately supported by preponderant evidence. Petitioner does seem to have suffered *some* kind of post-vaccination injury, which his expert characterizes as brachial neuritis.[4] However, even if I accept that proposed diagnosis for purposes of argument (since Respondent cites reasons to question its applicability), he has not demonstrated that it is more likely than not that this injury was due to the flu vaccine, or that onset occurred in a medically acceptable timeframe. And Petitioner's claim overall is insufficiently supported by medical record evidence that would corroborate his allegations.

I. Medical History

Petitioner was born on June 26, 1959. *See* Ex. 1 at 1. Prior to the vaccination at issue, his medical history was significant for osteoarthritis, chronic obstructive pulmonary disease, and a mass on his neck, which was surgically removed. Ex. 2 at 1.

From October 4-6, 2016, Mr. Bull was admitted to Providence Medical Center in Kansas City, Kansas, because of complaints of chest pain. *See* Ex. 2. During his hospital stay, Petitioner received the flu vaccine in his left arm. Ex. 2 at 9. The medical record and notes from this stay do not indicate any immediate adverse reaction or other change in circumstances. *See* Ex. 2.

On October 12, 2016, Petitioner reported to Terry Simmons, M.D., at Providence Medical Group to follow-up after his hospital stay. Ex. 1 at 3-4. Petitioner denied any further chest pain. *Id*. Petitioner was also treated for a rash on the top of his left hand that was itchy and getting bigger. *Id*. Dr. Simmons diagnosed him with ringworm and prescribed nystatin-triamcinolone. *Id.* Petitioner did not complain of any upper extremity pain, numbness, or tingling. *Id*.

[3] Although the original petition included a significant aggravation claim, there is no evidence in the record to support this allegation, and Petitioner did not argue it in his subsequent briefs, and thus appears to have abandoned it as grounds for an entitlement award. As such, I will not address it any further.

[4] The alleged injury is variously described as "Parsonage-Turner syndrome" or brachial neuritis, but it is recognized in medical science that these descriptive terms are interchangeable. *See Greene v. Sec. of Health & Hum. Servs.*, No. 11-631V, 2019 WL 4072110 at *2 n.3 (Fed. Cl. Spec. Mstr. Aug. 2, 2019), *mot. for review den'd,* 146 Fed. Cl. 655 (2020), *aff'd,* 841 Fed. App'x. 195 (Fed. Cir. 2020).

Mr. Bull presented to Dr. Simmons again on December 6, 2016, approximately two months post-vaccination. Ex. 1 at 1-2. At this visit, Petitioner now complained of "numbness and tingling after he got his flu shot on 10/4/16." *Id.* at 1. He specifically reported that he was dropping things because of the numbness, and complained that the pain radiated into his fingers and shoulder. *Id.* Dr. Simmons noted decreased sensation in the left arm to light touch, and tenderness in the area where Mr. Bull indicated he had received the vaccination, but that his grip strength was intact. *Id.* at 1-2. Dr. Simmons's assessment was neuropathy, and he was prescribed gabapentin twice a day for thirty days. *Id.* at 1.

On December 30, 2016, Mr. Bull reported to Shawn Lillig, M.D., at Heartland Urgent Care complaining of right flank pain that had started nine days before when he fell from a ladder at work. Ex. 4 at 2; Tr. at 60-61. Petitioner noted that the pain radiated to his gluteal area, and he had photographs of the progression of bruising that he experienced. *Id.* He also reported that he felt the worst pain in his life when he had to cough the day before. *Id.* A physical exam of his upper extremities reflected normal strength and tone, however, and it does not appear from this record that Mr. Bull repeated the complaints about vaccine-associated pain or other issues that he had reported earlier that same month. *Id.* at 3. Dr. Lillig's assessment was bronchitis and a fractured rib, and Petitioner was prescribed hydrocodone-acetaminophen. *Id.*

Mr. Bull has not filed any additional records for any subsequent time periods that would establish his receipt of additional medical treatment. However, Petitioner continued to fill prescriptions for gabapentin over the telephone, the last occurring April 9, 2017, when the refills ran out. Ex. 3 at 1. Petitioner has represented in his affidavit that he still suffers from occasional numbness, but started to feel better after renewing his prior prescription, which he filled on April 9, 2017. Ex. 6 at 2; Tr. at 67.

II. Fact Hearing

A fact hearing was held in this matter on July 11, 2019. *See* Docket Entry, dated July 11, 2019. The intent of the hearing was to provide Petitioner with the opportunity to be heard on the issue of onset.[5] *See* Status Report, filed March 22, 2019 (ECF No. 22).

A. Lisa Langland

Ms. Langland, Petitioner's ex-wife, provided testimony at the onset hearing. Tr. at 4-35. She began by describing her relations with Mr. Bull starting in October 2016. *Id.* at 4-5. Ms. Langland explained that she and Mr. Bull were married at the time, but she was living in her own personal residence, which was located less than one mile from Mr. Bull's residence. *Id.* at 5. Ms.

[5] Prior to the hearing, the witness provided statements indicating what their testimony would cover. *See*, Ex. 10; Ex. 11.

Langland described Mr. Bull as a hard-working middle-class person who typically did not go to the doctor or take medication. *Id.* at 5-6.

Ms. Langland then described an October 4, 2016 incident where Mr. Bull experienced chest pains. *Id.* at 6. Mr. Bull had called Ms. Langland at work to tell her that he was very short of breath, was having pains in his chest, was lightheaded, and concerned he was having a heart attack. *Id.* Because she knew Mr. Bull would not want to go to a doctor or an emergency room, she suggested he go to a local fire station where he would be able to receive some basic treatment at no cost. *Id.* at 6-7. There, it was immediately recommended that he go to the emergency room. Tr. at 7. After Ms. Langland got off of work, she personally transported Mr. Bull to the hospital for treatment, where he was admitted and stayed overnight. *Id.* The following morning, Ms. Langland testified that she visited Mr. Bull in the hospital to check on him, and his main complaint was about his arm. *Id.* at 8. She explained that Mr. Bull had received the flu shot at some point during his stay. *Id*. at 9. She remembered Mr. Bull describing it as the most painful shot he had ever had and that he really could not raise his arm that far. *Id.*

From October 6, 2016 forward, Ms. Langland explained, Mr. Bull complained about his arm still bothering him every day. Tr. at 11. She also described incidents in which Mr. Bull would apparently lose control of his hand and he would not even realize that he had dropped something until somebody pointed it out to him. *Id.* at 12. She explained that she moved back in with Mr. Bull on November 1, 2016, and that she observed that Mr. Bull's arm was a constant issue for him on a daily basis. *Id.* at 14. From December 2016 to February 2017, Ms. Langland stated that Mr. Bull was grabbing and rubbing his arm regularly. *Id.* at 17. By February 2017, however, Mr. Bull seemed to have more range of motion back in his arm and that he really seemed to improve after he began taking medication in January-February of 2017. *Id.* at 29, 33.

B. Michael Bull

Mr. Bull submitted an affidavit and provided testimony at the entitlement hearing. Petitioner's affidavit, filed as Ex. 6 on March 23, 2018 (ECF No. 6-6) ("Affidavit"); Tr. at 35-72.

Mr. Bull began his testimony by describing his hospital stay for chest pains in October of 2016. Affidavit at 1; Tr. at 36. He explained that at some point during the night, he was offered a flu shot, which he accepted in his left arm. Tr. at 37. He described it as very painful and he said he knew immediately something was not right. *Id.* He said that he informed the nurse of the pain in the arm he received the flu shot in and she responded by telling him that she too had a flu shot that day and her arm was also sore. *Id.* at 38. He believed the pain would go away on its own. *Id.* He went on to describe his pain the following day (October 6, 2016). *Id.* at 39. Mr. Bull explained that he did construction work on houses, and the day following his flu shot he could barely use his left arm at all, leading him to attempt to work one-handed. *Id.* He also testified that the pain increased

on the second day to a burning sensation that ran from his shoulder down to his hand. Affidavit at 1.

Mr. Bull described a subsequent doctor's appointment on December 6, 2016 that he had requested for his arm pain. Tr. at 41-42. He said the doctor thought a nerve may have been impacted during the October vaccine administration, and he was prescribed Gabapentin which he began taking immediately. *Id.* at 42; Affidavit at 2. The Gabapentin provided some relief, although not immediately. Tr. at 43. Around Christmas 2016, Mr. Bull testified, he still had trouble with his arm, and he remembered dropping ornaments on the floor without even realizing it. *Id.* He also recalled regularly dropping cigarettes out of his hand without noticing. *Id.* And he described an incident at work in which he fell off a ladder and suffered serious injuries for which he required medical attention. Affidavit at 2.

At the time of the hearing, Mr. Bull described the state of his arm as better, but added that he still gets tingling in his left fingers and he knows that he needs to put down whatever he is holding in his hand. Tr. at 45. He also testified that when he had run out of Gabapentin he had refilled the prescription, the last time being in April 2017. *Id.* But, because he had no insurance and the medication was expensive, he ended up relying on Ibuprofen more than anything. *Id.* He added that he does not regularly seek medical care because of the financial strain it puts on him. *Id.* at 46.

III. Expert Reports

A. Paul F. Nassab, M.D.

Dr. Nassab's report was the only report filed on Petitioner's behalf. Report, dated August 12, 2020, filed as Ex. 12 (ECF No. 45-1) ("Nassab Rep."). Dr. Nassab maintains that Petitioner suffers from Parsonage-Turner syndrome/brachial neuritis as a result of the October 2016 vaccination. Nassab Rep. at 2.

Dr. Nassab obtained his medical degree from Boston University School of Medicine. *See* Curriculum Vitae, filed as Ex. 15, dated August 13, 2020 (ECF No. 47-1). He completed a general surgery internship at Tripler Army Medical Center in Honolulu, Hawaii, and his residency at Medical College of Virginia in Richmond. Ex. 15 at 1. Dr. Nassab is licensed to practice medicine in Ohio, Virginia, and Missouri. *Id.* at 2. He has also published several journal articles and book chapters. *Id.* Currently, he works as an orthopedic surgery specialist at Orthopedic Health of Kansas City, P.C. Nassab Rep. at 1.

Dr. Nassab's two-page opinion is based solely on review of Mr. Bull's testimony and records extending back to 2011. Nassab Rep. at 1. Based on this review, Dr Nassab opines, "to a

reasonable degree of medical probability[,]" that Mr. Bull suffered from Parsonage-Turner syndrome. *Id.* at 2. Dr. Nassab describes Parsonage-Turner syndrome as quite painful. *Id.* Although the etiology is multifactorial, it has been attributed in the past to injections. *Id.* Dr. Nassab cites one case report in which brachial neuritis was observed three days after receipt of the flu vaccine. *Id.* (citing M. Shaikh et al., *Acute Brachial Neuritis Following Influenza Vaccination*, BMJ Case Rep. (2012), filed on August 12, 2020 as Ex. 14 (ECF No. 46-2) ("Shaikh")). According to Dr. Nassab, Petitioner's onset and timing of symptoms fits the description of post-vaccinal brachial neuritis, although he provides no elaboration as to why this is so. *Id.* Thus, Dr. Nassab concludes that vaccination was the likely prevailing factor in Petitioner's shoulder injury and impairment. *Id.*

B. Raymond S. Price, M.D.

Dr. Price, a neurologist and psychiatrist, prepared one five-page report on behalf of Respondent. Report, dated November 17, 2020, filed as Exhibit A (ECF No. 51) ("Price Rep."). Dr. Price reviewed the medical records filed in this case, the affidavits of the petitioner and his fact witnesses, as well as Dr. Nassab's expert report. Price Rep. at 1.

Dr. Price obtained his medical degree from the University of Pennsylvania, Perelman School of Medicine. *See* Curriculum Vitae, dated November 17, 2020, filed as Ex. B (ECF No. 51-6) ("Price CV"). He performed his residency in neurology as well as a fellowship in clinical neurophysiology at the Hospital of the University of Pennsylvania, Philadelphia. *Id.* at 1. Dr. Price is board certified in Psychiatry and Neurology, Neuromuscular Medicine, and Electrodiagnostic Medicine. *Id.* Currently, Dr. Price is co-director of the Neurohospitalist Division of the Department of Neurology at the University of Pennsylvania Health System. *Id.* He is also the attending physician of the outpatient neurology resident clinic and lecturer for neurology residents. *Id.* at 3.

Dr. Price began the discussion section of his expert report with a review of brachial neuritis/Parsonage-Turner syndrome. Price Rep. at 2. According to Dr. Price, brachial neuritis has a unifying clinical triad: an antecedent trigger; severe pain; and severe muscle weakness and wasting with the upper extremity, shoulder, and ipsilateral chest or bulbar muscles. *Id.* The severe unilateral upper extremity pain may last from a few hours to four weeks in duration. *Id.* Acute pain is followed by development of denervation, weakness, and atrophy of involved muscles. *Id.* Immunization, among other things, is a reported trigger. *Id.* Onset of symptoms following vaccination is typically 3-21 days. *Id.* Although the etiology of brachial neuritis is unclear, it is thought to be an immune-mediated inflammatory reaction. *Id.* at 1-2. As such, nerve conduction studies and needle EMG are critical to confirm the diagnosis and rule out other potential causes. *Id.* at 2.

Dr. Price then analyzed Mr. Bull's presentation of symptoms following vaccination. Price Rep. at 2. Dr. Price contends that there are several aspects of Mr. Bull's presentation that are *not*

consistent with a diagnosis of brachial neuritis. *Id.* First, there is no clinical evidence that Mr. Bull displayed the cardinal feature of muscle weakness and wasting. *Id.* When Petitioner was examined by Dr. Simmons on December 6, 2016, Petitioner's left grip strength was intact, and there was no comment on loss of left arm muscle bulk. *Id.* (citing Ex. 1 at 1-2). Similarly, Petitioner's upper extremity strength was normal when he was evaluated by Dr. Lillig on December 30, 2016. *Id.* (citing Ex. 4).

Second, Petitioner's left arm numbness without accompanying weakness is inconsistent with a diagnosis of brachial neuritis. Price Rep. at 3. According to Dr. Price, dropping objects out of the hand can be secondary to either hand and finger weakness or hand and finger numbness. *Id.* But considering the findings in the medical records that showed normal strength examinations by Drs. Simmons and Lillig, the most reasonable explanation would merely be hand and finger numbness rather than weakness. *Id.* Further, the record of Dr. Simmons's exam indicated a decreased left arm light touch sensation—also suggesting numbness. *Id.* While Dr. Price admitted that numbness can in rare cases be seen in brachial neuritis, numbness *without* weakness is inconsistent with the diagnosis. *Id.*

Third, Dr. Price distinguished Petitioner's reported inability to lift his arm due to neuromuscular weakness from weakness secondary to pain. Price Rep. at 3. Dr. Price opined that the most reasonable explanation for Mr. Bull's inability to lift his arm would be pain. *Id.* Dr. Price based this conclusion on the medical records indicating that Petitioner's upper extremity strength examination was normal. *Id.* (referring to Ex. 4). However, because Petitioner never obtained a needle electromyography (EMG), it was not possible to confirm the diagnoses of brachial neuritis and rule out other potential explanations. *Id.*

Dr. Price also opined that the time course of Mr. Bull's reported immediate presentation of symptoms was inconsistent with vaccination-caused brachial neuritis. Price Rep. at 4. According to Dr. Price, brachial neuritis typically begins days or a few weeks after vaccination, not immediately. *Id.*; P. Tsairis et al., *Natural History of Brachial Plexus Neuropathy; Report on 99 Patients*, 27 Archives of Neurology 109-172 (1972), filed as Ex. A Tab 3 on Nov. 17, 2020 (ECF No. 51-4) ("Tsairis"). This is because an immune-mediated process would require time for activation of the immune system. *Id.* Indeed, even in the Shaikh article referenced by Petitioner's expert, the case report subject's symptoms began no sooner than three days after vaccination, not immediately. *Id.* (citing Ex. 14). An immediate presentation of symptoms, according to Dr. Price, is more suggestive of direct trauma to a nerve or ischemia rather than injury caused by the vaccine itself. *Id.*

Finally, Dr. Price noted a lack of medical record proof confirming aspects of Petitioner's allegations. For example, there are no medical records filed in this case demonstrating that Mr. Bull has required further evaluation and management of his symptoms since April 2017. Price

Rep. at 4. There are also no medical records demonstrating that Petitioner required medications for neuropathic pain, like Gabapentin, beyond that same date, thus suggesting that Petitioner's injury had resolved by that time. *Id.*

IV. Procedural History

As noted above, the matter was initiated in March 2018. Respondent filed his Rule 4(c) Report on November 11, 2018 along with a Motion to Dismiss, arguing that (1) Petitioner had not clearly identified a diagnosis that was caused by the flu vaccination; (2) regardless of Petitioner's alleged injury, he had not provided a reliable medical theory of vaccine-causation; (3) there was not a logical sequence of cause and effect between Petitioner's alleged injury and the flu vaccination; (4) Petitioner otherwise had failed to establish a medically-appropriate temporal relationship between the flu vaccination and the onset of his alleged injury from which to infer causation; and (5) Petitioner failed to satisfy the severity requirement under the Act. (ECF No. 15, 16). Petitioner filed a response to Respondent's motion on December 14, 2018. (ECF No. 20).

A fact hearing was thereafter held in July 2019 in Kansas City, Missouri, to allow Mr. Bull the opportunity to flesh out some of his allegations, given that (as substantiated during that hearing) his practice was not to seek medical treatment regularly. After hearing testimony from Petitioner and his ex-wife, I informed the parties that I considered both witnesses honest, and deemed it likely based upon the available evidence that Petitioner's symptoms had begun immediately after he received the flu vaccine. *See* Mot. at 4. However, I did not make a formal fact ruling, and instead encouraged the parties to attempt to settle the claim, especially in light of litigation risk issues (which particularly cut against Mr. Bull, since he could not offer medical record evidence to substantiate many elements of his claim).

The parties could not bridge their gap, and therefore I ordered Petitioner to file an expert report in support of his claim. *See* Docket Entry, dated December 12, 2019. Dr. Nassab's report was filed in August 2020, and in response I ordered Respondent to indicate whether he would reconsider settlement or instead wished to seek some other form of case resolution. Docket entry, dated September 2, 2020. Respondent expressed the intent to file a rebuttal report and seek the claim's dismissal—and to that end, in November 2020 filed both Dr. Price's expert report and a motion for a ruling on the record dismissing the claim. The matter is now fully briefed and ripe for resolution.

V. Parties' Respective Arguments

Petitioner asserts that his October 5, 2016 flu vaccination caused him to suffer from brachial neuritis. Opp. at 4. Petitioner acknowledges that there is a lack of direct evidence for how the flu vaccine can cause brachial neuritis, but states that it is known that vaccines can cause the

condition from case reports. *Id.* at 5. Petitioner's expert, Dr. Nassab, offered medical literature—in the form of two case reports—to support his conclusion that Petitioner suffered from brachial neuritis as a result of his flu vaccination. *Id.* at 9. And, Petitioner offers a theory—that vaccines in general can cause local inflammation that could cause conditions like brachial neuritis under certain circumstances. *Id.* at 4. Moreover, Petitioner argues that because the Act does not require proof of causation that rises to the level of scientific certainty, he has made a satisfactory showing in this case. In addition, Petitioner argues that he has satisfied the six-month severity requirement based on the testimony provided and documentation that Petitioner continued to take medication to treat the vaccine caused injury for the required time period. *Id.* at 6-7.

Respondent, in contrast, asserts that Petitioner has failed to prove by preponderant evidence that the "vaccine-induced neuropathy" he allegedly suffered was caused by the receipt of his October 2016 flu vaccination. Mot. at 1. First, Respondent argues that Petitioner has not provided sufficient evidence that he suffered from a compensable diagnosis. *Id.* at 5. Respondent's expert, Dr. Price, explains that Petitioner's clinical presentation is not consistent with a diagnosis of brachial neuritis because Petitioner did not have medical evidence of the cardinal feature of brachial neuritis, muscle weakness and wasting. *Id.*

Second, Respondent argues that Petitioner has not offered a reliable medical theory or a logical sequence of cause and effect to meet the preponderance standard. Mot. at 6. Respondent critiques Dr. Nassab's opinion as conclusory, and failing to delineate a theory of how receipt of the flu vaccination can cause the injury. *Id.* at 7. Moreover, Dr. Nassab did not identify anything about Petitioner's clinical presentation or in his medical records that would indicate a logical sequence of cause and effect. *Id.*

Finally, Respondent argues that Petitioner has not established an appropriate timeframe to attribute causation. Mot. at 7. While, Dr. Nassab asserts that the onset and timing of Petitioner's symptoms fits the description of post-vaccinal brachial neuritis, he does not specify what an appropriate timeframe would be between receipt of the flu vaccine and onset of brachial neuritis symptoms. *Id.* at 8. And Respondent argues that Petitioner has not sufficiently demonstrated that his symptoms continued for six months or more, with the record suggesting that Petitioner's neuropathy had resolved approximately three months post-vaccination. *Id.* at 8.

VI. Applicable Law

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time

or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006). In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Secretary of Health and Hum. Servs.*, 418 F.3d 1274, 1278 (2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and

thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Andreu*, 569 F.3d 1367, 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury.

The Federal Circuit has consistently rejected the contention that the first *Althen* prong can be satisfied merely by establishing a proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." (citing *Moberly*, 592 F.3d at 1322)). Rather, this prong (like the other two) requires a preponderant showing. This naturally flows from the overarching fact that Program petitioners *always* have the ultimate burden of establishing their claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals.

Hibbard v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical

records was rational and consistent with applicable law"), *aff'd sub nom. Rickett v. Sec'y of Health & Hum. Servs.*, 468 F. Appx. 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Dep't of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

There are, however, situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("'[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent'") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything

reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *Lalonde v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

A special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion

proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for rev. denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. Appx. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

Expert opinions based on unsupported facts may be given relatively little weight. *See Dobrydnev v. Sec'y of Health & Hum. Servs.*, 556 F. Appx. 976, 992–93 (Fed. Cir. 2014) ("[a] doctor's conclusion is only as good as the facts upon which it is based") (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("[w]hen an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion")). Expert opinions that fail to address or are at odds with contemporaneous medical records may therefore be less persuasive than those which correspond to such records. *See Gerami v. Sec'y of Health & Hum. Servs.*, No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013), *aff'd*, 127 Fed. Cl. 299 (2014).

D. *Consideration of Medical Literature*

Petitioner has filed medical and scientific literature in this case, but not every filed item factors into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. Appx. 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Consideration of Comparable Special Master Decisions*

In reaching a decision in this case, I have taken into account other decisions issued by special masters (including my own) involving similar injuries, vaccines, or circumstances. I also

reference some of those cases in this Decision, in an effort to establish common themes, as well as demonstrate how such prior determinations impact my thinking on the present case.

There is no error in doing so. It is certainly correct that prior decisions from different cases do not *control* the outcome herein.[6] *Boatmon,* 941 F.3d at 1358–59; *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). Thus, the fact that another special master reasonably determined elsewhere, on the basis of facts not in evidence in this case, that preponderant evidence supported the conclusion that vaccine X caused petitioner's injury Y does not compel me to reach the same conclusion in *this* case. Different actions present different background medical histories, different experts, and different items of medical literature, and therefore can reasonably result in contrary determinations.

However, it is *equally* the case that special masters reasonably draw upon their experience in resolving Vaccine Act claims. *Doe v. Sec'y of Health & Hum. Servs.,* 76 Fed. Cl. 328, 338–39 (2007) ("[o]ne reason that proceedings are more expeditious in the hands of special masters is that the special masters have the *expertise and experience to know the type of information that is most probative of a claim*") (emphasis added). They would therefore be remiss in ignoring prior cases presenting similar theories or factual circumstances, along with the reasoning employed in reaching such decisions. This is especially so given that special masters not only routinely hear from the same experts in comparable cases but are also repeatedly offered the *same* items of medical literature regarding certain common causation theories. It defies reason and logic to obligate special masters to "reinvent the wheel", so to speak, in each new case before them, paying no heed at all to how their colleagues past and present have addressed similar causation theories or fact patterns. It is for this reason that prior decisions can have high persuasive value—and why special masters often explain how a new determination relates to such past decisions.[7] Even if the Federal Circuit does not *require* special masters to distinguish other relevant cases (*Boatmon,* 941 F.3d at 1358), it is still *wise* to do so.

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[6] By contrast, Federal Circuit rulings concerning legal issues are generally binding on special masters in all cases. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014). Special masters are also bound within a specific case by determinations made by judges of the Court of Federal Claims after a motion for review is resolved.

[7] Consideration of prior determinations is a two-way street that does not only inure to the benefit of one party. Thus, I would likely take into account the numerous decisions finding no association between vaccination and autism when confronted with a new claim asserting autism as an injury and have informed such claimants early in the life of their case that the claim was not viable for just that reason. But I would *also* deem a non-Table claim asserting GBS after receipt of the flu vaccine as not requiring extensive proof on *Althen* prong one "can cause" matters, for the simple reason that the Program has repeatedly litigated the issue in favor of petitioners.

F. *Evaluation of Expert Credentials and Professional Competence*

It is common in Program cases for special masters to evaluate competing expert opinions when deciding non-Table claims—and that process can be very difficult when the experts are equally well-credentialed and qualified to provide the opinion offered. Under such circumstances, resolution of a claimant's success in establishing causation turns on the comparative reliability of the scientific/medical contentions each side makes, rather than a measure of each particular expert's baseline qualifications against the other. *See, e.g., D'Tiole v. Sec'y of Health & Hum. Servs.*, No. 15-085V, 2016 WL 7664475, at *20 (Fed. Cl. Nov. 28, 2016) (determination that causation theory was unreliable did not arise from adequacy of Petitioner's expert, who was expressly deemed well-qualified to provide the opinion given), *mot. for review den'd,* 132 Fed. Cl. 421 (2017), *aff'd*, 726 F. App'x 809 (Fed. Cir. 2018).

In other circumstances, however, weighing the probative value of an expert's opinion fairly takes into account that same expert's qualifications or professional experience. This is most obviously necessary when an expert offers an opinion that plainly exceeds his training or individual competence. *Domeny v. Sec'y of Health & Hum. Servs.,* No. 94-1086V, 1999 WL 199059, at * 15 (Fed. Cl. Spec. Mstr. Mar. 15, 1999) (dentist not qualified to offer diagnostic opinion on whether petitioner had experienced a neuropathy), *mot. for review den'd,* slip op., May 25, 1999 (Fed. Cl.), *aff'd*, 232 F.3d 912 (Fed. Cir. 2000). But it can even be an issue with experts who possess immense and impressive credentials, and who in prior cases may have offered reliable opinions. *See, e.g.*, *Rolshoven v. Sec'y of Health & Hum. Servs.,* No. 14-439V, 2018 WL 1124737, at *21 (Fed. Cl. Spec. Mstr. Jan. 11, 2018) (otherwise-competent expert with significant Vaccine Program experience undermined his credibility in part with constant commentary about relevant legal standards to be applied in case).

G. *Determining Entitlement Via Ruling on the Record*

In accordance with the parties' agreement and my own assessment of how to best decide this case, I am resolving Petitioner's claim on the papers rather than via hearing. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs.,* No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy*

v. Sec'y of Health & Hum. Servs., No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. *Petitioner's Brachial Neuritis Diagnosis Was Not Preponderantly Established*

It is often necessary in many cases to determine the nature of the petitioner's injury—especially if the causal theory is dependent on establishing that a specific injury occurred. *Broekelschen*, 618 F.3d at 1345; *LaPierre v. Sec'y of Health & Hum. Servs.*, No. 17-227V, 2019 WL 6490730, at *16–17 (Fed. Cl. Spec. Mstr. Oct. 18, 2019). Since Petitioner's expert has opined that brachial neuritis best explains his injury, an analysis of his success in so establishing is required to adjudicate the claim.

In this case, there is limited evidence upon which to base the conclusion that Mr. Bull's injury likely constituted brachial neuritis. First, he was never so diagnosed—and little medical record evidence could be cited as consistent with that proposed diagnosis. Even if Dr. Simmons's assessment of Petitioner's injury as a generalized "neuropathy" is deemed arguably to include brachial neuritis, it was never confirmed, even that same month in December 2016 when Mr. Bull was treated for a different injury (although that fact might reasonably explain why the neuropathy was not discussed).

Second, Petitioner did not display an important feature of brachial neuritis: muscle weakness and wasting. *See* Ex. A at 3; Ex. 1 at 1-2 (December 6, 2016 evaluation by Petitioner's treater, Dr. Simmons, showed Petitioner's left grip strength intact, and he did not note that there was a loss of left arm muscle bulk); Ex. 4 at 3 (December 30, 2016 evaluation by Petitioner's treater, Dr. Lillig, showed Petitioner's upper extremities had normal strength and tone, and he did not note any loss of left arm muscle bulk). Dr. Price persuasively opined in his report that Petitioner lacked the required clinical indicia or other testing results (muscle atrophy or wasting, needle EMG study, etc.) that would confirm a diagnosis of brachial neuritis.

For the sake of argument, I shall assume herein that the injury Mr. Bull suffered was brachial neuritis. In addition, and as noted below, the fact evidence testimony is supportive of the conclusion that Petitioner experienced some kind of post-vaccination injury, suggesting in turn that the disposition of this matter should not solely arise from a determination that his preferred injury classification has not been preponderantly established. But it is clear from this record and the expert opinions that brachial neuritis does not "more likely than not" explain Petitioner's injury—and this could reasonably be grounds for the claim's dismissal, without any concern for his satisfaction of the *Althen* prongs.

II. *Petitioner Has Not Established His Onset Occurred in a Medically-Acceptable Timeframe*

Concurrent consideration of the proof offered in support of the first and third *Althen* prongs is often inherent to evaluating the acceptability of a proposed timeframe for vaccine-induced onset. This reasonably flows from the close relationship between the two. *See, e.g., de Bazan*, 539 F.3d at 1352 (the explanation for what is a medically acceptable timeframe for injury onset must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement)); *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 Fed. App'x. 952 (Fed. Cir. 2013).

If I address only the first, "can cause" prong in isolation, Petitioner's assertion that the flu vaccine could cause brachial neuritis is supported with some reliable evidence. To begin with, literature (in the form of case reports) filed in this case links the flu vaccine to brachial neuritis. *See e.g.*, Shaikh; P. Foye et al., *Electrodiagnostic Findings in Brachial Plexopathy After Influenza Vaccination*, WebmedCentral NEUROLOGY 2011; 2(2): WMC001530, filed on November 25, 2020 as Ex. 16 (ECF No. 52-1).

There are also other Program determinations in which a claimant has received compensation for this injury after vaccination, even though there is no Table claim for flu vaccine-caused brachial neuritis. *See e.g., Rickstrom v. Sec'y of Health & Hum. Servs*, No. 18-53V, 2021 WL 424446 (Fed. Cl. Spec. Mstr. Jan. 12, 2021) (decision on joint stipulation). And I have addressed non-Table claims involving this injury and other vaccines. *See,* e.g., *Greene v. Sec. of Health & Hum. Servs*., No. 11-631V, 2019 WL 4072110 (Fed. Cl. Spec. Mstr. Aug. 2, 2019) (tetanus vaccine not shown to have caused brachial neuritis (non-Table claim) because onset was not medically acceptable), *mot. for review den'd*, 146 Fed. Cl. 655 (2020), *aff'd*, 841 Fed. App'x. 195 (Fed. Cir. 2020); *Garner v. Sec'y of Health & Hum. Servs*., No. 15-063V, 2017 WL 1713184 (Fed. Cl. Spec. Mstr. Mar. 24, 2017) (Hepatitis A and B vaccines not shown to have caused brachial neuritis, given overly-long onset), *mot. for review den'd*, 133 Fed. Cl. 140 (2017). It is certainly *plausible* that the flu vaccine, like other vaccines, could cause brachial neuritis (although of course plausibility is not preponderance).

Nevertheless, Petitioner's prong one showing is far from robust, and not preponderantly established. Petitioner readily acknowledges in his brief that "[t]here may not be direct evidence of exactly how the influenza vaccine can cause brachial neuritis," and thus he relies more on case reports. Opp. at 5. Petitioner further states that "we know that the influenza vaccine, and vaccines in general, cause local inflammation that could cause conditions like brachial neuritis under certain circumstances." *Id*. Petitioner goes on to argue that because the Act does not require petitioners to present proof of causation to the level of scientific certainty, a satisfactory showing has been made in this case based on the assertions of Dr. Nassab and the filed case reports. But I have repeatedly

held that case reports, though relevant and sometimes helpful, are a kind of evidence having weak probative causation value. *See e.g.*, *Martin v. Sec'y of Health & Hum. Servs.*, No. 17-250V, 2020 WL 4815840 at *27 (Fed. Cl. Spec. Mstr. July 17, 2020). They are thus not enough *alone* to meet Petitioner's burden—and Dr. Nassab's fairly conclusory opinion did not provide them additional weight.

Moreover, even if I could find the "can cause" prong had been met, the third *Althen* prong proves a more conclusive stumbling block—for Petitioner has not presented sufficient reliable scientific or medical evidence establishing that an immediate post-vaccination onset of brachial neuritis symptoms is medically acceptable. As a factual matter, the evidence supports the conclusion that onset in this case was immediate.[8] As Mr. Bull testified at the fact hearing, "[the shot] was very painful. I immediately knew something wasn't right, immediately." Tr. at 37. Petitioner also testified about his left arm at work the next day, "[b]asically couldn't use it…I just kind of did what I could one-handed." *Id.* at 39. As I previously indicated, I found Petitioner and Ms. Langland to be credible and truthful in their testimony at the hearing.

An onset of Petitioner's symptoms immediately following administration of the flu shot is, however, inconsistent with a medically acceptable temporal relationship for vaccine-caused brachial neuritis. Price Rep. at 3; Shaikh; Nassab Rep. at 2. As Dr. Price established, onset of brachial neuritis symptoms following vaccination is typically 3-21 days. Price Rep. at 3; Tsairis. This is because an immune-mediated process would require time for activation of the immune system. Price Rep. at 4.

Petitioner did not rebut the contention that a one-day or less onset for brachial neuritis would not be medically acceptable. Dr. Nassab stated in conclusory fashion that "the onset and timing of [Petitioner's] symptoms fits the description of post-vaccinal brachial neuritis." Nassab Rep. at 2. But Dr. Nassab did not specify what an appropriate timeframe would be between receipt of a flu vaccine and onset of brachial neuritis symptoms, nor did he explain how an immune-mediated response could cause immediate symptoms. Petitioner otherwise argued in his brief that onset of brachial neuritis occurs "between 1-to-30 days post-vaccination." Pet. Reply at 12. But Petitioner derived this timeframe from case reports, which (as already noted) have far less probative value than other kinds of evidence. Neither Dr. Nassab nor the medical literature filed in support of Petitioner's claim have demonstrated how a presumptively immune-mediated process, which requires time for activation of the immune system, can cause immediate onset of brachial neuritis following flu vaccination. And I am aware of no Program decisions finding an immediate or one-day onset of brachial neuritis post-vaccination was reasonable.

[8] Immediate onset of pain post-vaccination *is* evidence of a different kind of injury common in the Vaccine Program—shoulder injury related to vaccine administration ("SIRVA"). SIRVA is also a recognized Table claim for flu vaccine recipients. *See Tenneson v. Sec'y of Health & Hum. Servs.,* No. 16-1664V, 2018 WL 3083140 (Fed. Cl. Spec. Mstr. Mar. 30, 2018). But the record *in this case* does not support the conclusion that Mr. Bull experienced a SIRVA injury, and Petitioner has not alleged SIRVA either.

In light of the above, even if I accepted that the flu vaccine could cause brachial neuritis—a determination not particularly well-supported by the evidence in this matter—I unquestionably cannot find, given the record, that the timeframe at issue *in this case* was medically acceptable, and thus Petitioner's claim cannot satisfy the third *Althen* prong.

III. *Althen Prong Two Has Not Been Satisfied*

I also do not find that Petitioner presented preponderant evidence to satisfy the second *Althen* prong. This prong requires a Vaccine Act claimant to establish a logical explanation of how the vaccine actually caused injury under the relevant facts. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

As noted, there are problems with Petitioner's favored diagnosis, vaccine-induced neuropathy/Parsonage Turner syndrome/brachial neuritis. But even accepting that classification of the injury, the record does not support the conclusion that Mr. Bull's injury was likely immune-mediated. The limited medical records and witness testimony do not contain any proof that an autoimmune process was underway, or that his initial symptoms reflected an immune-mediated response. Petitioner describes brachial neuritis as "an inflammatory condition that involves injury to the brachial plexus, a group of nerves that travel from the upper spine to the shoulder, arm, and hand." Pet.'s Sur-Reply at 7 (internal quotations omitted). The localized immune-mediated inflammation damages the nerves of the brachial plexus. *Id.* at 11. Thus, the condition should be accompanied by evidence, direct or indirect, of an inflammatory process that could be attributed to an immune reaction. But Dr. Nassab could not identify anything in Petitioner's clinical course that would allow that conclusion, and I see no other evidence in this limited record that would support the determination either.

IV. *Petitioner's Claim Overall Lacks Sufficient Record Corroboration*

A final point to be made about this claim is the overall absence of independent evidence, whether in the form of medical records or something else, to support Mr. Bull's contentions. As noted, I deemed him a credible witness, and I gave some weight to his contentions (supported by Ms. Langland) that he experienced some kind of injury after receiving the flu vaccine. The record shows he complained of this injury at a subsequent treater visit, and took medication for it as well. All of these determinations were reasons to allow the claim to progress, and to give Petitioner the opportunity to substantiate it with an expert opinion. And I have taken into account Petitioner's explanation at the fact hearing that he was not a person who regularly sought medical treatment—meaning that his claim would have to find non-medical record evidence for its substantiation. Tr. at 67.

Nevertheless, the overall record in this case is quite thin, and that insufficiency reasonably weighed down the Petitioner in his efforts to meet the preponderant standard. Indeed—not only was there hardly any evidence to conclude he likely had brachial neuritis, as Dr. Nassab alleged, or that the flu vaccine could cause that injury in a day's time, but the evidence of the injury's severity was also quite weak. *See* Section 11(c)(1)(D); *Watts v. Sec'y of Health & Hum. Servs.*, No. 17-1494V, 2019 WL 4741748 at *3 (Fed. Cl. Spec. Mstr. Aug. 13, 2019). Petitioner's sincerity in establishing some kind of injury simply could not be bulwarked with enough other evidence to find entitlement for him.

CONCLUSION

The Vaccine Act permits me to award compensation only if a petitioner alleging a "non-Table Injury" can show by medical records or competent medical opinion that the injury was more likely than not vaccine-caused. The medical record in this case reveals that Petitioner's injury presents too close in time from vaccination to plausibly suggest an immune-mediated link between the two, nor has Petitioner presented a persuasive or reliable causation theory that fits the facts. There is therefore insufficient evidence to support an award of compensation, and I must hereby **DISMISS** this claim.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accordance with this decision. [9]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[9] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.